REMARKS

This Response, filed in reply to the Office Action dated November 14, 2007, is believed to be fully responsive to each point of objection and rejection raised therein. Accordingly, favorable reconsideration on the merits is respectfully requested.

Claims 1-50 are all the claims pending in the application, of which Claims 1-36, 41, 42, 45-47 and 49 are withdrawn from consideration. Claims 37-40, 43, 44, 48 and 50 are rejected. Claims 1-37 and 48 are canceled without prejudice or disclaimer. Claims 38-47, 49 and 50 are amended. Support for these amendments can be found throughout the specification, and at least at the following.

Support for the amendments to Claim 38 can be found at, for example, paragraph [0013], lines 19, 20 and 32 of the published specification. Support for the amendment to Claim 39 is implicitly and inherently disclosed in paragraph [0027], Table 2, of the published specification, by disclosure of primers VVrecF2 and VVrecR2. The amendments to Claims 40-47 and 49 are to improve clarity. Claim 50 has been amended to remove dependencies from canceled claims.

Information Disclosure Statements

Applicants thank the Examiner for returning a signed and initialed copy of the PTO Form SB/08 that accompanied the Information Disclosure Statement filed July 5, 2007.

Withdrawn Rejections

Applicants thank the Examiner for withdrawal of the rejection of Claims 37-40, 43, 44, 48 and 50 under 35 U.S.C. § 112, second paragraph, as set forth in the Office Action mailed May 30, 2007.

Claims 39, 40, 43 and 50 are Definite Under 35 U.S.C. § 112

On page 3 of the Office Action, Claims 39, 40, 43 and 50 are rejected under 35 U.S.C. § 112 for allegedly being indefinite.

It is asserted that recitation of "wherein a region that contains, at a high frequency, a position(s) unique to Vibrio vulnificus as specified in claim 38 is used" is vague. Claims 40, 43 and 50 are rejected on the same ground as they ultimately depend from Claim 39.

In making the rejection, it is also asserted that recitation of "wherein a region that contains, at a high frequency, a position(s) unique to Vibrio vulnificus as specified in claim 38 is used" is an intended use.

Solely to advance prosecution, and without acquiescing in the rejection, Applicants herewith amend Claim 39 to specifically recite the frequency of nucleotides unique to *Vibrio vulnificus* over a given polynucleotide length. Support for such an amendment is inherently present in the specification by the reduction to practice of primers VVrecF2 and VVrecR2, as shown in Tables 2-4. One of skill in the art would instantly recognize that the VVrecF2 and VVrecR2 primers each contain a region wherein at least two positions within 21 continuous nucleotides of SEQ ID NO:3 are unique to *Vibrio vulnificus* as compared to other bacteria of the genus *Vibrio*. Specifically, VVrecF2 primer contains the unique positions 138 and 153, whereas the VVrecR2 primer contains the unique positions 228 and 237. Applicants respectfully submit that the amendment overcomes the rejection.

Withdrawal of the rejection is respectfully requested.

Claims 38-40, 43, 44, 48 and 50 are Adequately Described Under 35 U.S.C. § 112

On page 4 of the Office Action, Claims 37-40, 43, 44, 48 and 50 are rejected under 35 U.S.C. § 112, first paragraph, for allegedly lacking adequate written description.

With regard to Claim 37, it is asserted that recitation of "[a] fragment of a polynucleotide having a sequence of SEQ ID NO: 3" encompasses any polynucleotide having a sequence of SEQ ID NO:3, which allegedly may be a mere two nucleotide stretch of SEQ ID NO:3. Further, it is asserted that recitation of "wherein the fragment comprises two or more nucleotides at any of positions 9, 81, 138..." can encompass a nucleic acid sequence that contains two or more nucleotides found at the recited positions in SEQ ID NO: 3.

Without agreeing with the rejection, and solely to advance prosecution, Applicants herewith cancel Claim 37, thus mooting the rejection of this claim. Further, Applicants herewith amend Claims 38-44. Claims 38 and 39 have been amended to recite that the claimed primers comprise a region of at least 15 continuous nucleotides of SEQ ID NO:3, or the complement thereof, and that said region comprises at least two positions unique to *V. vulnificus* selected from defined positions in SEQ ID NO:3. As these "positions" are inherently defined by their location in SEQ ID NO:3, and because the claims recite a primer comprising a contiguous sequence containing at least two of the defined positions, Applicants submit that the amendment overcomes the rejection. Support for the amendments to Claims 38 and 39 can be found in at least paragraph [0013], lines 19 and 20, and in the Examples described in the specification using primers VVrecF2 and VVrecR2.

Withdrawal of the rejection is respectfully requested.

Claims 38-40, 44 and 48 are Patentable Under 35 U.S.C. § 102(b)

On page 8 of the Office Action, Claims 37-40, 44 and 48 are rejected under 35 U.S.C. § 102(b) as being anticipated by GenBank Accession number GI:16565115, published online on November 1, 2001.

With specific regard to Claim 37, it is alleged that Accession number GI:16565115 discloses a "fragment of a polynucleotide having a nucleotide sequence of SEQ ID NO: 3" as recited by instant Claim 37. It is further asserted that Accession number GI:16565115 was obtained from *Vibrio vulnificus*, and thus can be used for designing a specific gene amplification primer or a specific probe.

With regard to Claims 38 and 40, it is alleged that Accession number GI:16565115 contains at least 15 continuous nucleotides, including nucleotides found at positions 133-153 of SEQ ID NO: 3, and would be suitable for use as a gene amplification primer. Further, with regard to Claim 44, the Examiner asserts that Accession number GI:16565115 contains SEQ ID NO:17.

With regard to Claim 39, it is alleged that recitation of "wherein a region that contains, at a high frequency, a position(s) unique to Vibrio vulnificus as specified in claim 38 is used" is merely an intended use, and does not structurally distinguish the claimed primer over that disclosed by Accession number GI:16565115.

With regard to Claim 48, it is alleged that positions 238-258 of Accession number GI:16565115 correspond exactly to positions 133-153 of SEQ ID NO:3 and that Accession number GI:16565115 also contains 15 or more continuous nucleotides and thus can be used as a probe for detecting, quantifying or identifying *Vibrio vulnificus*.

Solely to advance prosecution, and without agreeing with the rejection, Applicants herewith cancel Claims 37 and 48, and amend Claim 38 to recite that the claimed primer is "not more than 40 nucleotides in length." Support for the amendment to Claim 38 can be found within paragraph [0013], lines 32-34 of the published specification, where it is disclosed that "gene amplification primers [are] preferably 20 or more nucleotides, and further preferably 20 or more nucleotides and 40 or fewer nucleotides." Accession number GI:16565115 only discloses a 543 nucleotide fragment, as admitted in the Office Action mailed November 14, 2007. Accordingly, Accession number GI:16565115 does not teach each and every element of Claim 38 as amended, as is required to maintain an rejection under 35 U.S.C. §102.

Withdrawal of the rejection is therefore respectfully requested.

Claims 38-40, 43, 44, 48 and 50 are Patentable Under 35 U.S.C. § 102(b)

On page 11 of the Office Action, Claims 37-40, 43, 44, 48 and 50 are rejected under 35 U.S.C. § 102(b) as being anticipated by Random Primer 24, sold by New England Biolabs.

Specifically, it is asserted that each vial of Random Primer 24, as sold by NEB, contains every possible 24-nucleotide sequence. Thus, the Examiner concludes that Random Primer 24, as sold by NEB, would contain every possible gene fragment imaginable that is 24 nucleotides in length, and thus inherently anticipates Claims 37-40, 43, 44 and 48.

Further, with regard to Claim 50, it is alleged that Random Primer 24 is itself a kit, as it was a commercial product sold as early as 1998. The Examiner asserts that the 24-mer random primer could also be used for detecting, quantifying or identifying *Vibrio vulnificus*, such as by synthesizing a labeled probe by random priming from a *Vibrio vulnificus* nucleic acid template.

Applicants respectfully disagree, and traverse the rejection in view of the following remarks.

Applicants respectfully submit that the Examiner's inherent anticipation rejection is inapt. Although the Examiner alleges that the random oligonucleotide composition (i.e., Random Primer 24) contains the claimed oligonucleotides, the Examiner has not presented *any* evidence, other than a theoretical possibility, that the claimed sequence is present in the random oligonucleotide composition. However, such is not the standard for inherency. The Examiner has not set forth *any* evidence to show that the claimed primers are *necessarily* present in the random primer composition. The Examiner's rationale, and indeed his calculations, depend entirely on the assumption that each possible primer is synthesized with equal efficiency. However, the Examiner presents no evidence why random primer synthesis follows a uniform distribution pattern.

Further, Applicants respectfully submit that Random Primer 24 cannot serve as an anticipatory reference in view of the following remarks. One factor in whether a reference qualifies as anticipatory prior art is whether the prior art reference clearly names the claimed species. Pursuant to M.P.E.P. § 2131.02, "[a] genus does not always anticipate a claim to a species within a genus." (Emphasis added.) In this regard, the disclosure of the Random Primer 24 product represents merely a generic chemical formula, which encompasses an enormously large genus containing 281,474,976,710,656 (4^{24}) possible combinations.

As set forth in M.P.E.P § 2131.02, the standard for whether a genus anticipates a species was addressed in *In re Petering*, 301 F.2d 676 (C.C.P.A. 1962). In *In re Petering*, the prior art disclosed a chemical genus having a limited number of substituent groups that represented either hydrogen or alkyl radicals, and an R group containing an OH group. The court held that the

subgenus, containing only 20 compounds and a limited number of variations in the generic chemical formula, inherently anticipated a claimed species within the genus because "one skilled in [the] art would... envisage each member" of the genus. Thus, *In re Petering* is factually distinguished from the instant case, because the limited number of compounds of Petering was 20, whereas the number of compounds disclosed by Random Primer 24 is 281,474,976,710,656. Thus, one of skill in the art would not instantly envisage the claimed primers from the 281,474,976,710,656 possible combinations, without any guidance in this regard.

Further, Applicants refer the Examiner to the holdings in *Eli Lilly and Co. v. Zenith Goldline Pharma et al.* Nos. 05-1396, 1429, and 1430 (Fed. Cir. 2006) and *Sanofi-Synthelabo v. Apotex, Inc.* (06-1613, Fed. Cir. 2006).

In *Eli Lilly and Co. v. Zenith Goldline Pharma et al.*, the anticipatory reference cited by the defendants disclosed a wide-ranging series of clozapine-like compounds, which encompassed literally millions of compounds. The Court held that the generic disclosure "did not place [the claimed compound] in the possession of the public" because it did not spell out a "limited class of compounds that enabled a person of ordinary skill in the art to at once envisage each member of this limited class." Applicants note that in comparison to the millions of compounds disclosed in *Eli Lilly and Co. v. Zenith Goldline Pharma et al.*, the genus disclosed by Random Primer 24 discloses over 281 trillion distinct compounds, with no direction that would lead one of ordinary skill in the art to instantly envisage the claimed primer sequences.

Further, In *Sanofi-Synthelabo v. Apotex, Inc.*, Apotex argued that the active ingredient in Plavix, which is clopidogrel, was disclosed through a broad generic formula in U.S. Patent No. 4,529,596 ("the '596 patent"). However, the Federal Circuit held that the '596 patent failed to expressly describe the specific chemical structure at issue. Similar to *Eli Lilly and Co. v. Zenith*

Goldline Pharma et al. discussed above, the Court distinguished the case from Petering. The Court held that the generic disclosure lacked a "pattern of preferences" present in each of the distinguished cases, which "would limit the generic formula ... to a narrow class of compounds that includes [the claimed species]."

Thus, in view of the above, Applicants submit that the rejection is clearly at odds with the decisions of the Federal Circuit. Considering the enormous number of compounds disclosed by Random Primer 24, and absent a specific teaching or suggestion that would allow one of skill in the art to further narrow the genus, Applicants submit that the Examiner has erred in a finding of anticipation. Rather, we do not believe that of the 281,474,976,710,656 different compounds disclosed by Random Primer 24, one of skill in the art would "at once envisage" the claimed oligonucleotides, as is required for a generic chemical formula to anticipate a claimed species. The claimed sequences need not be necessarily present in the random primer composition because as stated by the Examiner's reference, they are *random* primers, however, the Examiner has erred in assuming that the distribution of primer sequences in the random primer composition is uniform.

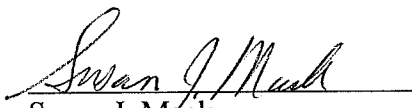
Thus, Applicants respectfully submit that the anticipation rejection is improper.

Withdrawal of the rejection is therefore respectfully requested.

In view of the above, reconsideration and allowance of this application are now believed to be in order, and such actions are hereby solicited. If any points remain in issue which the Examiner feels may be best resolved through a personal or telephone interview, the Examiner is kindly requested to contact the undersigned at the telephone number listed below.

The USPTO is directed and authorized to charge all required fees, except for the Issue Fee and the Publication Fee, to Deposit Account No. 19-4880. Please also credit any overpayments to said Deposit Account.

Respectfully submitted,



Susan J. Mack
Registration No. 30,951

SUGHRUE MION, PLLC
Telephone: (202) 293-7060
Facsimile: (202) 293-7860

WASHINGTON OFFICE
23373
CUSTOMER NUMBER

Date: February 14, 2008